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510(k) Summary of Safety and Effectiveness

Manufacturer/Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Sally Foust Regulatory Affairs Project Manager Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1251 Fax: 239/598.5508 Email: sally.foust@arthrex.com
Trade Name	Arthrex Univers II Shoulder Pegged Glenoid
Common Name	Shoulder Prosthesis
Product Code -Classification Name	**KWS** – Prosthesis, Shoulder, semi constrained metal/polymer, cemented **HSD** – Prosthesis, Shoulder, hemi-humeral, metal, uncemented
Predicate Devices	Arthrex Univers II Shoulder Prosthesis, K071032 Arthrex Univers Shoulder Prosthesis, K010124
Device Description and Intended Use	The Arthrex Univers II Shoulder Pegged Glenoid is manufactured in three sizes from UHMWPE. The glenoid articular (lateral) surface is concave and articulates with the humeral head of the Univers or Univers II humeral stems. The fixation (medial) surface is convex and is designed with three pegs for cement interdigitation fixation. The Arthrex Univers II Shoulder Prosthesis is indicated in replacements(s) when conditions include severe pain or significant disability resulting from degenerative, rheumatoid, traumatic disease, or injury of the glenohumeral joint; non-union humeral head fractures of long duration; irreducible 2- and 4- part proximal humeral fractures; avascular necrosis of the humeral head; or other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable.

	The glenoid components are designed for cemented fixation in the joint and must only be used with an appropriate bone cement.
Substantial Equivalence Summary	The Arthrex Univers II Shoulder Pegged Glenoid is substantially equivalent to the predicate Arthrex Univers Shoulder Prosthesis in which the basic features and intended uses are the same. Any differences between the Arthrex Univers II Shoulder Pegged Glenoid and the predicate Arthrex Univers Shoulder Prosthesis or Univers II Shoulder Prosthesis are considered minor and do not raise questions concerning safety and effectiveness. Based on the information submitted, Arthrex, Inc. has determined that the new Arthrex Univers II Shoulder Pegged Glenoid is substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2009

Arthrex, Incorporated
% Ms. Sally Foust, RAC
Regulatory Affairs Project Manager
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K083435
Trade/Device Name: Arthrex Univers II Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal-polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: KWS, HSD
Dated: May 29, 2009
Received: June 3, 2009

Dear Ms. Foust:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3 Indications for Use Form

Indications for Use

510(k) Number: K083435

Device Name: **Arthrex Univers II Shoulder Prosthesis**

The Arthrex Univers II Shoulder Prosthesis is indicated in replacements(s) when conditions include severe pain or significant disability resulting from degenerative, rheumatoid, traumatic disease, or injury of the glenohumeral joint; non-union humeral head fractures of long duration; irreducible 2- and 4-part proximal humeral fractures; avascular necrosis of the humeral head; or, other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable.

The glenoid components are designed for cemented fixation in the joint and must only be used with an appropriate bone cement.

Prescription Use _X_ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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